IN THE UNITED STATES COURT OF FEDERAL CLAIMS

GILEAD SCIENCES, INC., *Plaintiff*, v. UNITED STATES, *Defendant.*	Civil No. 1:20-cv-499 Senior Judge Charles F. Lettow

DEFENDANT'S AMENDED TRIAL WITNESS LIST

Pursuant to the Court's Scheduling Order of April 11, 2022, ECF No. 65, Defendant, the United States (the Government), hereby submits its amended trial witness list. The Government is submitting this amended list because it inadvertently served an earlier version of its list with its pretrial memorandum (ECF 95-1). This list includes only minor changes from the list filed on May 13, 2022 (ECF 77) and clarifies certain issues raised by Gilead counsel and by Gilead's first amended witness list (ECF 96).

While an address for every live witness is provided, personal phone numbers have not, as all witnesses (with the exception of current or former Gilead employees) can be contacted through Government counsel.

A. Defendant *will* call the following witnesses for its case-in-chief or for rebuttal in the above-referenced case, the trial of which begins on June 23, 2022:

1. Dr. Walid Heneine (live)
Chief, Laboratory Branch,
NCHHSTP/DHAP,
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333

Time[1] needed for direct examination: 3 hours

Dr. Heneine will testify live regarding the research and development efforts leading to the filing of patent applications related to the HHS Patents (as well as relevant patent prosecution efforts). Dr. Heneine will also testify on the influence of the results of CDC's 4323 Safety Study and TDF2 Study on the prosecution and content of the HHS Patents.

2. Dr. James Rooney (live and/or by designation)
118 Westridge Drive
Portola Valley, California, 94028

Time needed for direct examination: 2 hours

The Government will call Dr. James Rooney as an adverse witness, live and/or by designation, regarding his discussions, involvement and knowledge of CDC's research and development efforts leading to the HHS Patents, as well as PrEP development efforts generally. The Government will also seek Dr. Rooney's testimony regarding his

[1] The Government's estimates of direct examination time are present projections and estimates based on Gilead's expected case-in-chief. The Government reserves the right to change these projections based on Gilead's pre-trial memorandum and other future pre-trial submissions as well as the Court's rulings on Gilead's motions *in limine*, which seek to exclude all expert testimony from Kimberly Schenk.

involvement in the negotiation, execution and compliance by the parties of the material transfer agreements (MTAs) and clinical trial agreements (CTAs) at issue.

3. Dr. Robert Janssen (live)
Chief Medical Officer
SVP Clinical Development, Regulatory and Medical Affairs
Dynavax Technologies
2100 Powell Street, Suite 900
Emeryville, California 94608

Time needed for direct examination: 1 hour

Dr. Janssen will testify live regarding CDC's research and development efforts leading to the HHS Patents, as well as any earlier CDC efforts related to PrEP. Dr. Janssen will also testify regarding his decision to leave CDC and join Gilead in 2008, including, but not limited to, his execution of a Gilead patent disclosure agreement in May 2008. Dr. Janssen will also testify regarding his discussions and work regarding PrEP while employed at Gilead from 2008 to 2010.

4. Dr. Tara Kirby (live)
Director
NIH Office of Technology Transfer
6701 Rockledge Dr., Suite 700
Bethesda, Maryland 20892

Time needed for direct examination: 2 hours

Dr. Kirby will testify live regarding NIAID's efforts in prosecuting the HHS Patents and foreign equivalents, licensing the HHS Patents, and in otherwise making Gilead aware of the HHS Patents.

5. Suzanne S. Shope, Ph.D (live)
Boehringer Ingelheim Animal Health USA Inc.
3239 Satellite Blvd NW
Duluth, Georgia 30096

Time needed for direct examination: 1.5 hours

Dr. Shope will testify live regarding CDC's efforts to license the HHS Patents, including inclusion and discussion of relevant patent applications in various CDC licensing brochures beginning in 2006. Dr. Shope will also testify regarding the dissemination of those brochures both electronically and by hard copy to potential licensees.

6. Lisa Blake-Dispigna (live)
Technology Transfer Specialist
Technology Transfer Office,
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333

Time needed for direct examination: 1.5 hours

Ms. Blake-Dispigna will testify live regarding the drafting of language in MTAs at issue as well as execution and recordation of MTAs and CTAs at CDC, including but not limited to, efforts by CDC's Office of Administrative Services to monitor ongoing MTAs and CTAs both generally and with regard to MTAs and CTAs at issue.

7. Dr. Robert M. Grant (live)
Professor, UCSF School of Medicine
513 Parnassus Ave, HSE
San Francisco, California 94143

Time needed for direct examination: 1.5 hours

Dr. Grant will testify live as a fact and expert witness regarding (1) his background and experience in PrEP research (including, but not limited to, the iPrEx trial and his interactions with Dr. Marcus Conant regarding Conant's PrEP efforts) and (2) his

expert opinions on the significance of 4323 Safety Study as compared to HHS Patents generally as well as in obtaining FDA approval for the PrEP indication for Truvada®.

8. Kimberly Schenk (live)
Vice President
Charles River Associates
One South Wacker Drive
34th Floor
Chicago, Illinois 60606

Time needed for direct examination: 3 hours

Ms. Schenk will testify live as an expert witness regarding (1) her background and experience and (2) her expert opinions on the harm, or lack thereof, emanating from the alleged breaches of the asserted MTAs and CTAs. Ms. Schenk's testimony will be consistent with her expert reports in this case.

9. Dr. Sean Sheridan (live)
Principal
Charles River Associates
One South Wacker Drive
34th Floor
Chicago, Illinois 60606

Time needed for direct examination: 3 hours

Dr. Sheridan will testify live as an expert witness regarding (1) his background and experience and (2) his expert opinions on practices by technology transfer professionals in addressing intellectual property notice provisions in MTAs and CTAs and the harm, or lack thereof, emanating from the alleged breaches of the asserted MTAs and CTAs. Dr. Sheridan's testimony will be consistent with his expert report in this case.

10. James Carmichael
Carmichael IP, PLLC
8000 Towers Crescent Drive, 13th Floor
Tysons, Virginia 22182

Time needed for direct examination: 2 hours

Mr. Carmichael will testify live as an expert witness regarding (1) his background and experience and (2) his expert opinions on PTO practices and procedures, including but not limited to, the relative success of particular procedures forwarded by Gilead's expert. Mr. Carmichael's testimony will testify consistent with his expert report in this case.

11. Gregg Alton (live and/or by designation)
225 Chestnut Street
San Francisco, California 94133

Time needed for direct examination: 3 hours

Mr. Alton will testify live and/or by designation regarding Gilead's awareness of the HHS Patents, Gilead's efforts to resolve disputes with the Government over the HHS Patents, and Gilead's interest in and efforts to promote PrEP products from 2005 until the present.

B. Defendant *may* call the following witnesses for its case-in-chief or for rebuttal in the above-referenced case:

1. Dr. William (Bill) Lee (live or by designation)
2735 Baker Street
San Francisco, California 94123

Time needed for direct examination: 1 hour

Dr. Lee may testify as an adverse witness, live or by designation, regarding his interactions with Dr. Heneine during the execution of relevant MTAs and the research and development efforts leading to the HHS Patents. Dr. Lee may also testify regarding Gilead's patent monitoring efforts, including, but not limited to, a Derwent Alert he received regarding a patent application related to the HHS Patents.

2. Dr. Jeremiah Mitzelfelt (live)
NIAID Technology Transfer and Intellectual Property Office
Suite 6D
5601 Fishers Lane, MSC 9804
Rockville, Maryland 20892-9804

Time needed for direct examination: 1 hour

Dr. Mitzelfelt may testify live regarding NIAID's efforts in prosecuting the HHS Patents and foreign equivalents, licensing the HHS Patents, and in otherwise making Gilead aware of the HHS Patents.

3. Dr. Norbert Bischofberger (live or by designation)
983 Barriolhet Avenue
Hillsborough, California 94010

Time needed for direct examination: 1 hour

Dr. Bischofberger may testify live or by designation as an adverse witness regarding his discussions, involvement and knowledge of CDC's research and development efforts leading to the HHS Patents, as well as PrEP development efforts generally. Dr. Bischofberger may also testify regarding Gilead's interest and efforts in promoting PrEP commercially from 2005 to present. The Government may also seek Dr. Bischofberger's testimony regarding his involvement in the negotiation, execution and compliance by the parties of the MTAs and CTAs at issue.

4. Dr. Michael Miller
5 Applewood Lane
Portola Valley, California 94028

Time needed for direct examination: 1 hour

Dr. Michael Miller may testify live or by designation as an adverse witness regarding his discussions, involvement and knowledge of CDC's research and development efforts leading to the HHS Patents, as well as PrEP development efforts generally. The Government may also seek Dr. Miller's testimony regarding his involvement in the negotiation, execution and compliance by the parties of MTAs executed with the Government after Gilead alleges it became aware of the HHS Patents.

5. Dr. Madeline Miller (represented by Gilead's counsel)
333 Lakeside Drive
Foster City, California 94404

Time needed for direct examination: 1 hour

Dr. Miller may testify as an adverse witness regarding Gilead's efforts to negotiate the CTAs at issue, including but not limited to, their intellectual property provisions.

6. Dr. Marta Ackers (live)
PHI/CDC Monitoring and Evaluation Fellow
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, Georgia 30333

Time needed for direct examination: 1 hour

Dr. Ackers may testify live regarding the drafting of the 4323 CTA, including, but not limited to the intellectual provisions of that agreement.

7. Any custodian of records or other qualified witness needed to authenticate or otherwise address the admissibility any exhibit offered by the Government.

Time needed for direct examination: Less than 1 hour

The Government is willing to discuss stipulations and arrangements with Gilead so as to avoid calling such witnesses at trial.

C. In addition to the potential designated testimony listed above, the Government also intends to designate deposition testimony from the following witnesses in support of its case-in-chief or for rebuttal purposes:[2]

1. Dr. Dana Pizzuti (former Gilead employee)

The anticipated designations will relate to Gilead's actions and decisions, at different points in time, in seeking (or not seeking) a PrEP indication for Truvada® and Descovy®.

2. Kavitha Parthasarathy (Gilead)

The anticipated designations will relate to projections and forecasts of sales of Truvada® and Descovy®.

3. Sukeerthi Seetharaman (Gilead)

The anticipated designations will relate to Gilead's process for monitoring publications, applications and/or patents relating to Gilead's business and/or use of pharmaceutical products.

4. Manish Bisaria (Gilead)

The anticipated designations will relate to revenue Gilead has received from sales of Truvada® and Descovy®.

[2] The Government also reserves the right to counter-designate any deposition testimony designated by Gilead.

5. Melissa Koomey (Gilead)

The anticipated designations will relate to Gilead's efforts to promote Truvada® for PrEP, including, but not limited to, efforts to educate the public and raise awareness about appropriate PrEP use.

6. Stefania Attard (Gilead)

The anticipated designations will relate to the execution and purpose of Dr. Janssen's patent disclosure form and how that record is maintained and used by Gilead as well as more general testimony about the use and maintenance of this employee form at Gilead.

7. Dr. Michael Hitchcock (former Gilead employee)

The anticipated designations relate to Dr. Hitchcock's knowledge and involvement with the relevant CDC PrEP research (including the research leading to the HHS Patents) as well as his involvement in the drafting, negotiation, execution, and donation of Gilead study drugs under MTAs and CTAs, including, but not limited to, the MTAs and CTAs at issue.

8. Martha Vazquez (Gilead)

The anticipated designations will relate to Gilead's process for executing and administrating MTAs between 1996 and 2009 and Gilead's internal records relating to MTAs, including but not limited to records related to relevant publications and communications with investigators.

The Government reserves the right to amend and supplement this list as it learns of new information relevant hereto, including, but not limited to, discussions with

Gilead's counsel. In particular, the Government believes that its decisions on whether to call certain witnesses by designation or through live testimony will be informed by further discussions with Gilead. The Government further reserves the right to modify this list based on any later stipulations agreed to by the parties.

Dated: June 10, 2022

Respectfully submitted,

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